

Appl. No. : 10/623,875  
Filed : July 21, 2003

### REMARKS

Claims 14 through 20 stand pending in the present application. In response to the Office Action mailed November 2, 2005, Claim 14 has been amended herein. No claims have been added or deleted.

In the Office Action, Claims 14 through 20 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,571,089 to Crocker.

However, due to the profoundly different intended use of Applicant's present invention compared to the catheter disclosed by Crocker, Applicant's claims as amended herein recite features which are nowhere disclosed in Crocker.

Crocker relates to "a low profile balloon dilatation and/or drug delivery catheter, having a temporary stent for permitting perfusion while positioned within the vascular system". See Crocker at Column 1 lines 12 through 15. The goal was to produce a catheter "which has a minimal deflated or insertion profile for permitting access to remote or highly occlusive lesions, and which at the same time permits sufficient perfusion to minimize the occurrence of ischemic episodes while the balloon is inflated." See Column 1 lines 63 through 67.

The goal of providing a balloon with a low crossing profile for transluminal positioning, but having a maximally dimensioned perfusion lumen for use during balloon dilatation was achieved by providing an axially moveable support which may be selectively positioned within the balloon, to maintain patency of the perfusion lumen during balloon dilatation. See, for example, Column 2 lines 41 through 48:

Preferably, a tubular support is additionally provided for maintaining the perfusion conduit in the second, enlarged diameter. The support is in one embodiment disposed proximally of the balloon when the balloon is in the first, reduced diameter. The support is moveable distally to a position within the balloon to maintain the perfusion conduit in the second, enlarged diameter.

The foregoing structure is illustrated in Figures 14 and 15, cited by the Examiner. In Figure 14, the axially moveable support 160 is shown retracted proximally of the inflatable balloon 142.

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This allows the balloon to be folded into a minimal crossing profile. In Figure 15, the axially moveable support 160 has been distally advanced such that it spans the length of the balloon 142. In doing so, it provides an enlarged central lumen 156 for permitting perfusion from perfusion openings 154 on the proximal side of the balloon 142 and perfusion openings 152 on the distal side of the balloon 142. Perfusion openings 152 are provided on an elongated distal neck 146, which tapers distally at 148 to an introduction segment 150. Although not provided with a reference number in Figures 14 and 15, the distal end of the introduction segment 150 is illustrated as being provided with a radiopaque marker 38 in the form of an annular marker band. See Column 5 lines 48 through 51, and Figure 1.

Thus, the axially moveable support 160 in Crocker is adapted to support an enlarged perfusion lumen between a proximal series of perfusion openings 154 and a distal perfusion segment 144 having a plurality of perfusion openings 152. This entire support assembly is displaced proximally from the distal end of the catheter, which includes taper 148 and a small, fixed diameter introduction segment 150 surrounded by a marker band. At least the taper 148 and introduction segment 150 containing the marker band are unchanged in diameter throughout the axial range of motion of the axially moveable support 160.

Crocker is seeking to support the perfusion path through the length of the balloon, by resisting inward pressure from the inflated balloon which is when perfusion is desirable. Crocker therefore had no reason, and provided no teaching, to, among other things, advance the support 160 sufficiently far distally that it would open up the diameter of the introduction segment 150 and marker band.

Applicant's amended Claim 14 recites, *intra alia*, the following (emphasis added):

An opening on the distal end of the aspiration lumen;  
a distal section on the body in which the aspiration lumen including the opening on the distal end is movable between a first, reduced inside diameter . . . and a second, enlarged inside diameter for aspirating material.

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Applicant's present claimed invention is unconcerned with the problem of providing perfusion across the length of an inflated balloon, such as during angioplasty, stent placement and/or drug delivery. Instead, Applicant's invention is directed to the problem of providing a catheter having a low crossing profile format such as for transluminal navigation to the site of an occlusion, and enlarging the inside diameter of at least a distal portion of a lumen as well as the diameter of the distal opening to optimize aspiration of debris, manipulation of tools or implants etc. following placement of the catheter. For this reason, Applicant's claimed invention relates to a catheter in which the central lumen as well as the distal opening are enlargeable in order to optimize functionality.

No where does Crocker disclose or suggest the omission of introduction segment 150, or taper 148, which are positioned distally of the most distal position of the axially moveable support 160. Nor does Crocker suggest deleting the marker band, which would prevent radial expansion of the introduction segment 150.

Accordingly, Applicant respectfully submits that the present claimed invention is neither disclosed or suggested by the '089 to Crocker, and withdrawal of the outstanding rejections is respectfully requested.

In the Office Action, the Examiner additionally objected to paragraph 6, as containing a misspelling of the word "stroke". In response, Applicant has submitted a substitute paragraph 6, in which this misspelling has been corrected.

In addition, the Examiner indicated that references listed in the specification have not been properly identified in accordance with 37 C.F.R. § 1.98(b). As a consequence, Applicant has reviewed the specification and an updated Information Disclosure Statement has been submitted concurrently herewith.

In view of the foregoing, Applicant respectfully submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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